skilled in the art to feed a 1α-hydroxylated vitamin D compound as part of a daily diet because an oral administration to a dairy cow of a 1α-hydroxylated vitamin D compound is known from the '312 and '446 prior art; and because (2) it is known to administer a 1α-hydroxylated vitamin D compound in a diet containing low phosphorus to a cow in the dry period and through to parturition. The Applicant, however, respectfully disagrees for the following reasons.

Applicant's claim 1 specifically requires both a feed that contains about 0.3% by weight or less of an inorganic phosphorus supplement as well as an effective amount of a 1α-hydroxylated vitamin D compound. Both of these ingredients are fed to a dairy cow as part of a daily diet, and such daily diet is maintained throughout the cow's lactation period. The fact that claim 1 calls for feeding a very low percentage of inorganic phosphorus supplement together with a 1α-hydroxylated vitamin D compound during the cow's lactation period cannot be found in the prior art, and distinguishes claim 1 from what is taught in the prior art.

More specifically, DeLuca et al '312 discusses phosphate levels in three locations. First, at column 1, lines 21-22, it is noted that a decrease in blood phosphate level is one of the manifestations of milk fever disease. Secondly, at column 1, lines 60-67, DeLuca et al '312 states that one proposal for treating milk fever disease has been to feed a low calcium diet or to feed a high phosphate ration, but this technique is said to be impractical because it is necessary to feed cattle a high calcium diet during their non-lactating periods to replenish the calcium depleted by previous milkings. In any event, Applicant is not claiming the feeding of high phosphorus rations, but instead claims just the opposite, i.e. a low phosphorus diet. Finally, the DeLuca et al '312 reference refers to phosphorus in the example at column 3, lines 15-25 wherein it is stated that cows were fed a diet in the dry period of high calcium and low phosphorus. This diet was also maintained throughout the parturition portion of the experiment. It is important to note, however, that DeLuca et al '312 does not teach or mention that a low phosphorus diet can continue to be fed to a dairy

cow throughout the cow's lactation period. The example at column 3 of DeLuca et al '312 merely states that low phosphorus was fed "in the dry period" and "throughout the parturition portion of the experiment." It never mentions or suggests that a low phosphorus diet could be fed to a diary cow during the cow's lactation period.

With respect to DeLuca et al '446, this reference again refers to a decrease in blood phosphate levels as being one characteristic of milk fever disease at column 1, lines 18-19. The '446 patent also refers to feeding a high phosphate ration at column 1, lines 55-63. Again, Applicant is claiming just the opposite. Finally, at column 4, lines 9-12, DeLuca et al '446 refers to a diet which was fed to the cows in the example which contained greater than 100g calcium and less than 45g phosphorus daily. Again, although not specifically stated in the '446 description, the diet referred to at column 4, lines 9-12 was clearly fed during the dry period. Thus, once again this diet is not being administered during the lactation period of dairy cows. Instead, it is being administered immediately prior to calving and during the dry period of dairy cows. Further, it should be noted that a diet containing less than 45g phosphorus daily is not a "low phosphorus diet." It is important to note that Applicant is claiming 0.3% by weight or less of inorganic phosphorus supplement and not total phosphorus in the cow's diet. Thus, a statement such as that found in column 4, lines 9-12 of the '446 patent does not teach or suggest a diet containing less than 0.3% inorganic phosphorus supplement.

Thus, neither of the two cited references teaches or suggest the use of both a 1α-hydroxylated vitamin D compound in combination with less than 0.3% by weight of an inorganic phosphorus supplement. Further, neither reference teaches the use of such a combination as part of a daily diet fed to a cow during the cow's lactation period.

As discussed in Applicant's specification, much of the phosphorus in plant foods and feeds passes through the GI tract of the animal and is excreted in the feces. In animal husbandry, which includes diary cows, this is accounted for in diet formulation by providing an inorganic phosphorus source in a feed supplement which is added to the

normal diet to meet the animal's minimum phosphorus requirements. Since supplemental inorganic phosphorus is a relatively expensive ingredient in an animal's diet, its reduction and/or elimination would be desirable from a cost standpoint. Further, in dairy cows, such reduction of inorganic phosphorus cannot be made at the expense of milk yields. In the past, one skilled in the art would not have fed a low phosphorus diet to an animal such as dairy cows because 0.3% or less of phosphorus would not have met the minimum phosphorus requirements of the animal. As previously stated in the prior Amendment dated October 17, 2001, a normal diet contains about 0.9% phosphorus. Thus, Applicant's claim 1 which calls for less than 0.3% phosphorus is a significant drop, and there is simply no suggestion to use such a low phosphorus as part of a daily feed to lactating cows that can be found in either the '312 or the '446 references.

The Examiner indicates that the data in the specification is expected rather than unexpected. However, one skilled in the art would clearly not feed a ration to an animal which would not meet what is considered to be the minimum phosphorus requirements, i.e. about 0.9% phosphorus. Otherwise, the phosphorus levels would not be sufficient to provide adequate nutrition for the animal. Therefore, why would one skilled in the art feed a diet containing 0.3% or less of inorganic phosphorus supplement when the normal amount is 0.9%, and especially when knowing that 0.9% has been thought to be the required amount to provide the minimum phosphorus requirements for such animals? As stated in Applicant's specification, a reduction of inorganic phosphorus cannot be made at the expensive of milk yields. The data found in Applicant's specification shows that even though the diet contained low phosphorus, milk production was maintained. To one skilled in the art, this is an unexpected result since it was presumed in the past that one needed to feed at least 0.9% phosphorus to maintain milk production. The feeding of such low phosphorus levels, with the result that milk production is maintained, is clearly an unexpected result which would not have been predicted by one skilled in the art in view of the minimal amount of phosphorus being fed to the animal.

An effort has been made to place this application in condition for allowance and such action is earnestly requested.

Respectfully submitted,

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